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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/711,784	11/13/2000	Chris De Bruijn		8210

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EXAMINER

MCKANE, ELIZABETH L

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 03/13/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/711,784

Applicant(s)

DE BRUIJN ET AL.

Examiner

Leigh McKane

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 46-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 60 is/are allowed.
- 6) ☒ Claim(s) 46-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Specification

1. The amendment filed 31 December 2002 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: In the amendment to claim 52, the recitation that "said microbicidal concentration does not color or dilate an eye in contact with said solution" is considered to be new matter because it is not supported by the original disclosure.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 52 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The original disclosure does not support the recitation in amended claim 52 that "said microbicidal concentration does not color or dilate an eye in contact with said solution".

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 46 and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamakoshi et al (EP 812592 A1).

Yamakoshi et al teaches a hydrogen peroxide-free ophthalmic composition containing proanthocyanidins in an amount of 0.01-10 % (100-100,000 ppm). See page 6, lines 7-9. As shown in Formulation Example 1 (page 9, lines 1-12), the eye drops contain sodium chloride, an osmotic agent.

6. Claims 52, 53, and 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Ismail. Ismail teaches an ophthalmic composition containing berberine,

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Hydroxypropylmethylcellulose (a viscosity altering agent), and sodium chloride (an osmotic agent). See Example 11, pages 13-14. It is noted that the term "contact lens" in the preamble is merely a functional recitation of the intended use of the composition.

7. Claim 58 is rejected under 35 U.S.C. 102(e) as being anticipated by Hofmann et al (U.S. Patent No. 5,817,630).

Hofmann et al teaches a hydrogen peroxide-free ophthalmic solution containing 0.05 0.2% (500-2000 ppm) lipoic acid. See col.2, lines 31-32. Although not disclosed, the amount of lipoic acid used by Hofmann et al is a preservative-effective amount and thus inherently acts as a preservative.

8. Claim 59 is rejected under 35 U.S.C. 102(e) as being anticipated by Squires (U.S. Patent No. 6,355,684).

Squires discloses an ophthalmic composition containing Echinacea extract in an amount of 0.2-60% (2000-600,000 ppm). See col.3, lines 35-41; col.4, lines 11-18, line 31, lines 62-64; col.6, lines 36-41. Although not disclosed to be used as a preservative, the amount of Echinacea employed by Squires is inherently a preservative amount.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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10. Claims 47-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamakoshi et al as applied to claim 46 above, and further in view of Hofmann et al.

Yamakoshi et al teaches that the inventive therapeutic compositions can contain thickeners (viscosity altering agents), isotonicity inducing agent (osmotic agent), and various other adjuncts. See page 5, lines 55-59. Yamakoshi et al does not specifically teach use of these in an ophthalmic composition. Hofmann et al discloses an ophthalmic composition that contains a sequestering agent EDTA for eliminating heavy metal binding and improving lens pliability, a viscosity altering agent PVA for increasing solution adherence to the corneal surface, and a surfactant, known for improving surface contact and dispersion. As the composition of Yamakoshi et al, like Hofmann et al, is directed to preventing and treating eye disorders, it would have been obvious to include the adjuncts of Hofmann et al therein.

11. Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamakoshi et al and Hofmann et al, as set forth above and further in view of Chiou (U.S. Patent no. 5,182,258).

The combination *supra* teaches an ophthalmic composition employing surfactants but does not disclose using saponin as the surfactant. Chiou discloses an ophthalmic composition which may contain "surfactants such as saponins" (col.8, lines 64-65). As saponin is a surfactant safe for use in the eye, it would have been obvious to one of ordinary skill in the art to use a saponin as the surfactant of Yamakoshi et al with Hofmann et al.

12. Claims 54 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ismail in view of Hofmann et al.

Ismail teaches an eye drop composition but does not teach the use of a sequestering agent

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or a wetting agent therein. Hofmann et al discloses an ophthalmic composition that contains a sequestering agent EDTA for eliminating heavy metal binding and improving lens pliability and a surfactant, known for improving surface contact and dispersion. As the composition of Ismail, like Hofmann et al, is directed to preventing and treating eye disorders, it would have been obvious to include the adjuncts of Hofmann et al therein.

13. Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ismail and Hofmann et al, as set forth above and further in view of Chiou (U.S. Patent no. 5,182,258).

The combination above teaches an ophthalmic composition employing surfactants but does not disclose using saponin as the surfactant. Chiou discloses an ophthalmic composition which may contain "surfactants such as saponins" (col.8, lines 64-65). As saponin is a surfactant safe for use in the eye, it would have been obvious to one of ordinary skill in the art to use a saponin as the surfactant of the combination.

Allowable Subject Matter

14. Claim 60 is allowed.

Response to Arguments

15. Applicant's arguments filed 31 December 2002 have been fully considered but they are not persuasive.

16. With respect to Hofmann et al, the Examiner submits that it is immaterial whether or not Hofmann et al recognizes the microbicidal effect of lipoic acid in the composition. As lipoic acid is present in a preservative-effective amount, it anticipates the claim. Similarly, the amount

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of Echinacea employed by Squires is a preservative-effective amount and thus, anticipates the claim.

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 703-305-3387. The examiner can normally be reached on Monday-Wednesday (7:15 am-4:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 703-308-2920. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



Leigh McKane
Primary Examiner
Art Unit 1744

elm
March 11, 2003